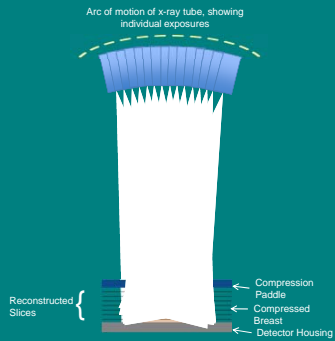
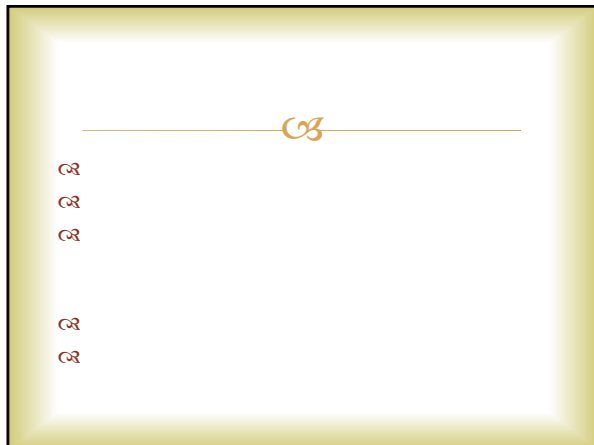




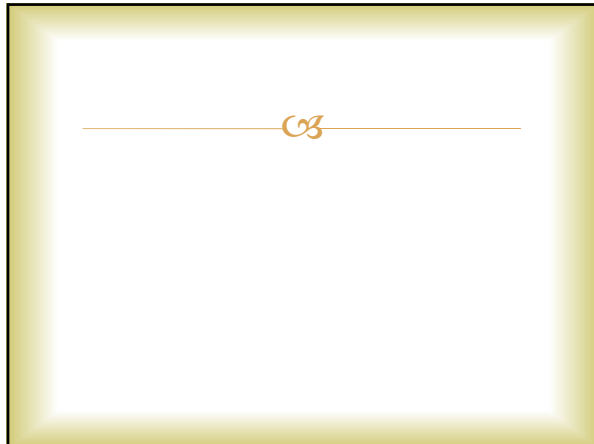
3D Principle of Operation

- X-ray tube moves in an arc across the breast
- A series of low dose images are acquired from different angles
- Total dose approximately the same as one 2D mammogram
- Projection images are reconstructed into 1 mm slices



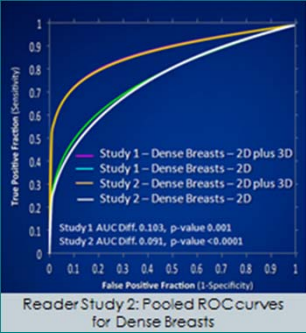






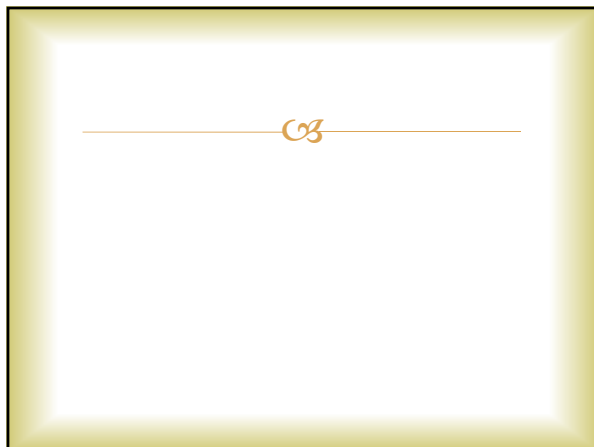
Why Dense Breasts

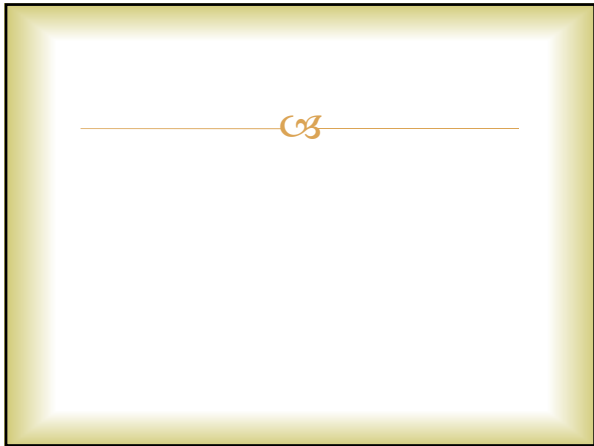
- Initially thought only significant benefit to dense breasts
- Later discovered benefit for fatty breasts as well

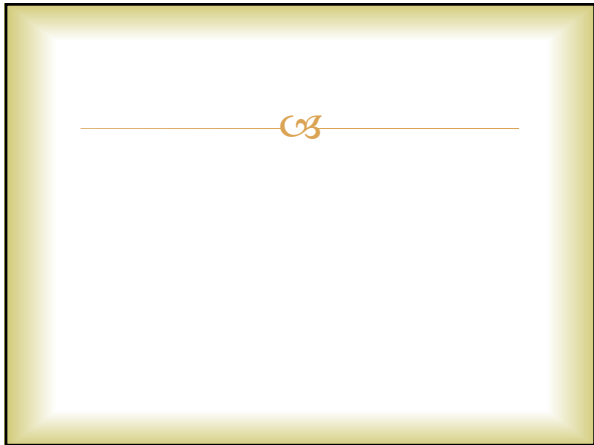


Reader Study 2: Pooled ROC curves for Dense Breasts

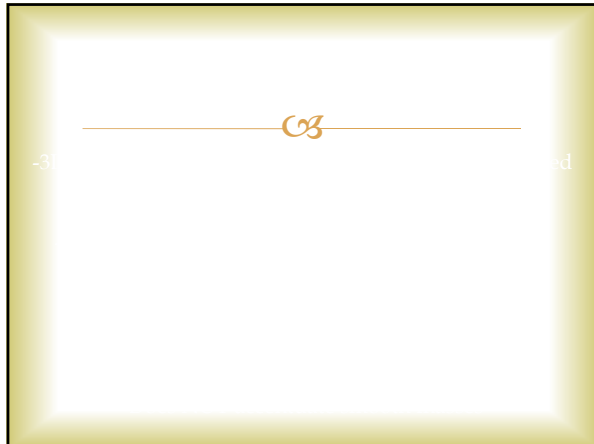
The graph shows four ROC curves for dense breasts. The y-axis is 'True Positive Fraction (Sensitivity)' and the x-axis is 'False Positive Fraction (1-Specificity)'. The curves are: Study 1 - Dense Breasts - 2D plus 3D (red), Study 1 - Dense Breasts - 2D (blue), Study 2 - Dense Breasts - 2D plus 3D (green), and Study 2 - Dense Breasts - 2D (orange). The red and green curves are significantly higher than the blue and orange curves, indicating better performance for the 2D plus 3D combination. Text on the graph: Study 1 AUC Diff 0.103, p-value 0.001; Study 2 AUC Diff 0.091, p-value < 0.0001.











*C-view Synthesized 2D Image

How does it work?

- Perform a standard tomosynthesis scan (existing system)
- Reconstruct tomosynthesis slices (existing system)

~60 Tomosynthesis Slices

Reconstruction Algorithm

15 Projection Images

*Not approved for sale in the United States

C-view Synthesized 2D Image

How does it work?

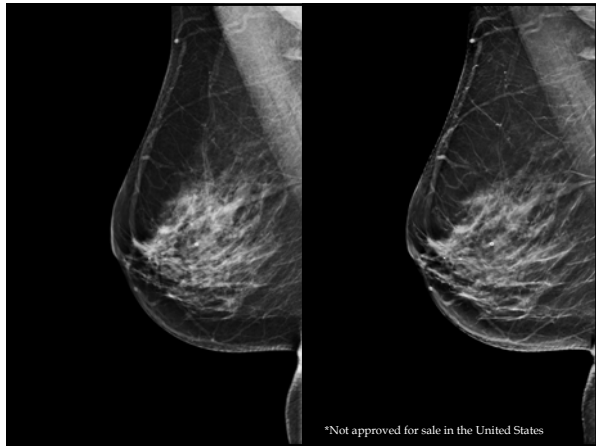
- Perform a standard tomosynthesis scan (existing system)
- Reconstruct tomosynthesis slices (existing system)
- Synthesize 2D image (C-View)
Similar to Maximum Intensity Projection (MIP) as done with MRI images

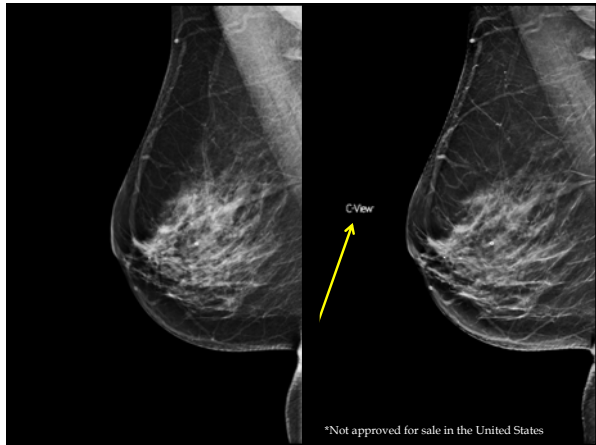
~60 Tomosynthesis Slices

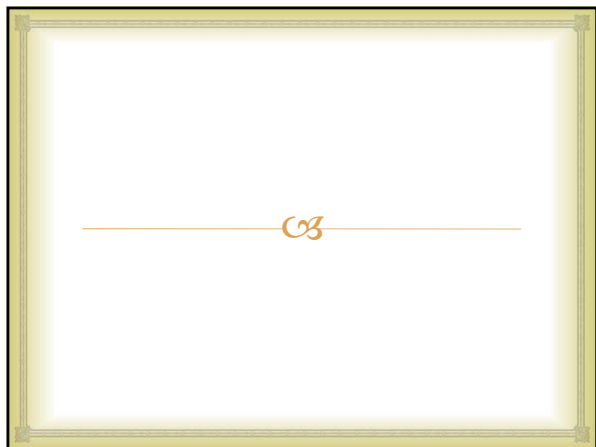
Image Summation

C-View

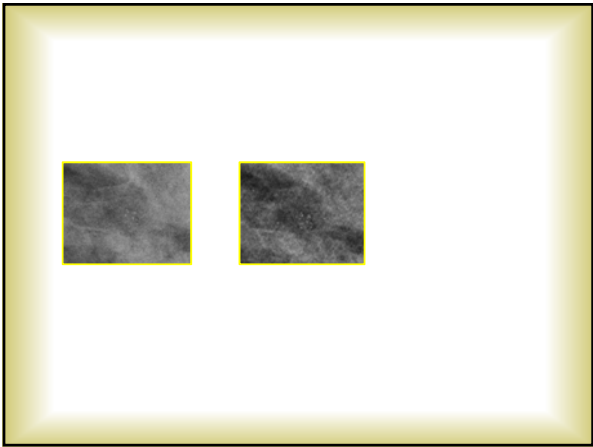
*Not approved for sale in the United States

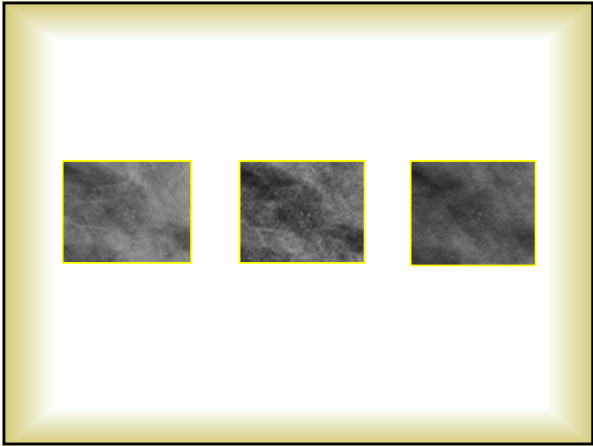




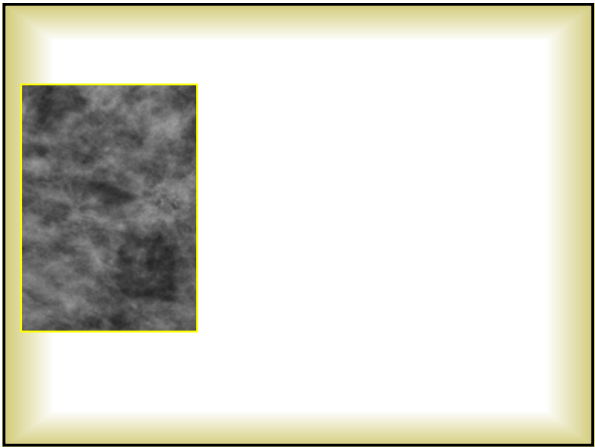


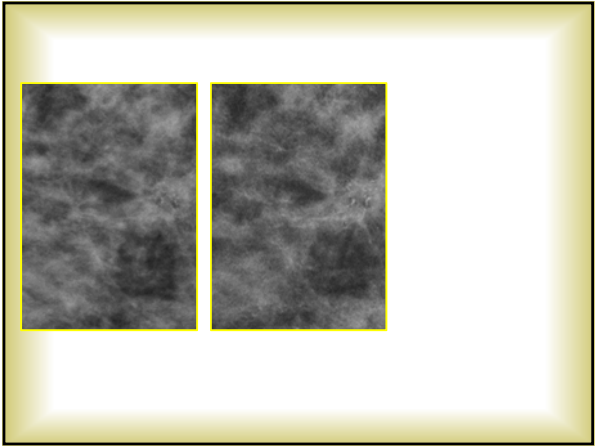








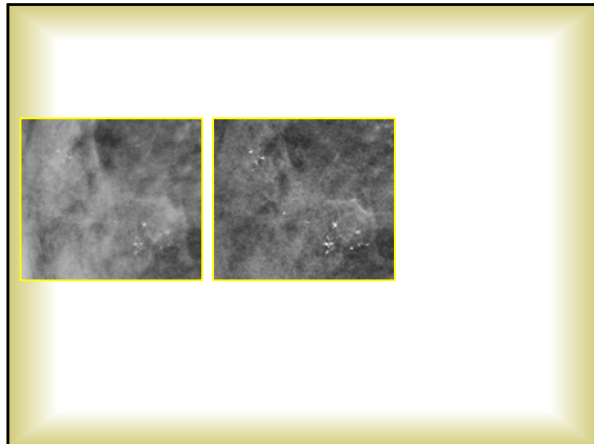


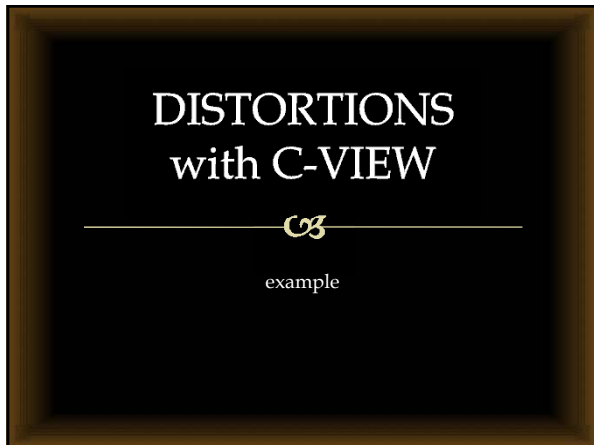








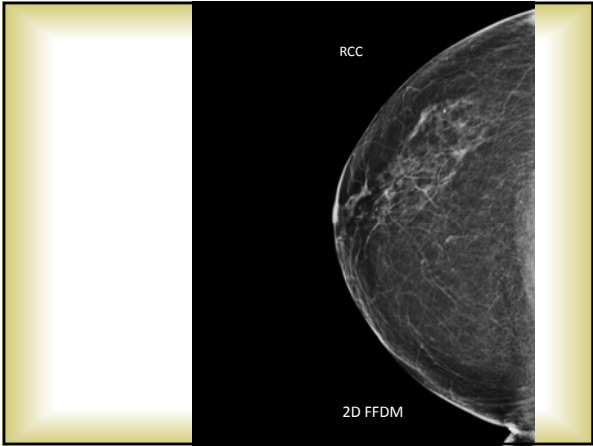


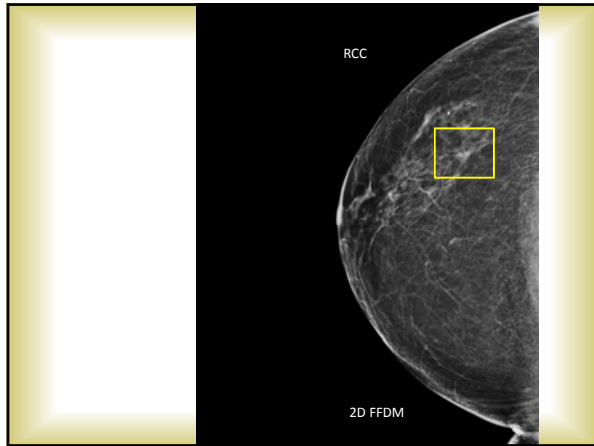


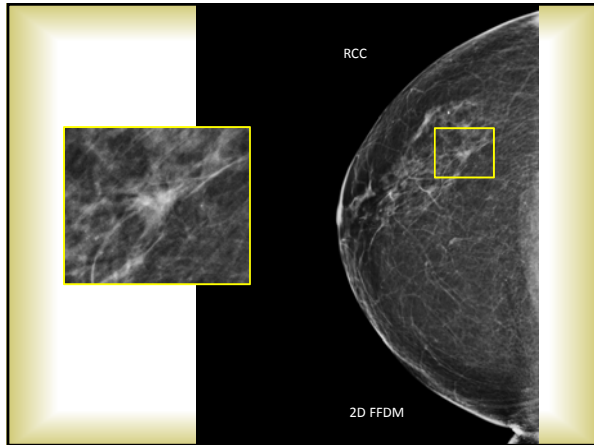


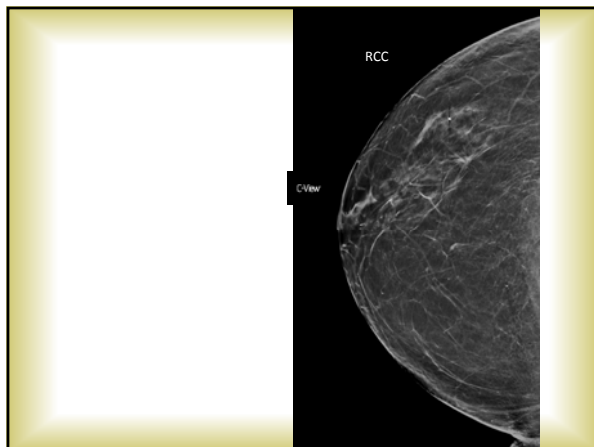


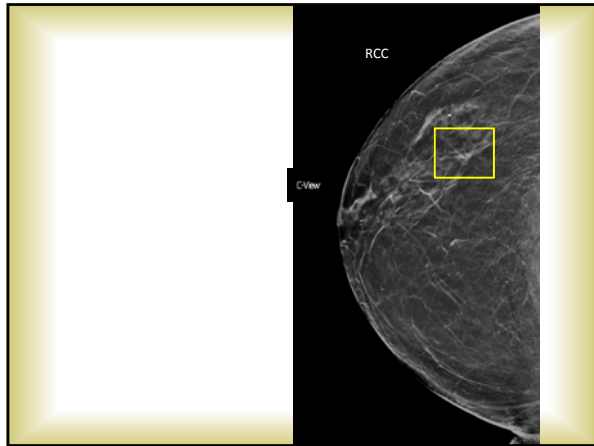


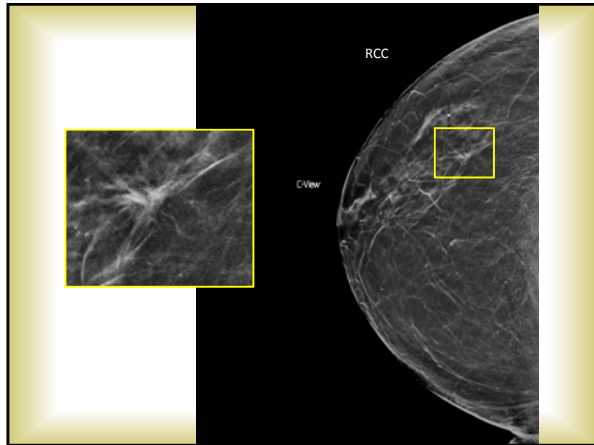




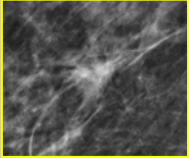








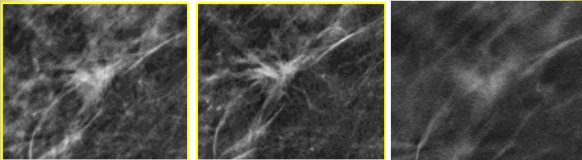


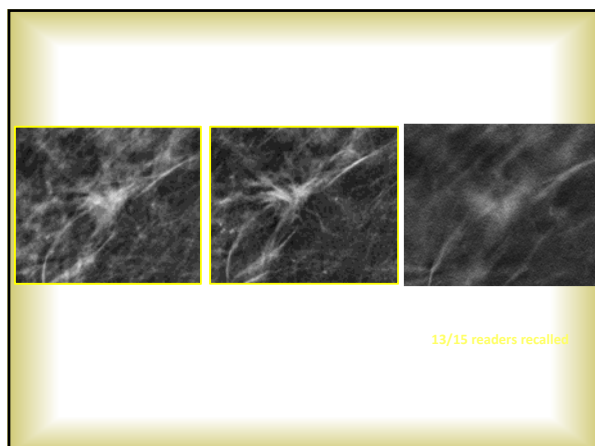


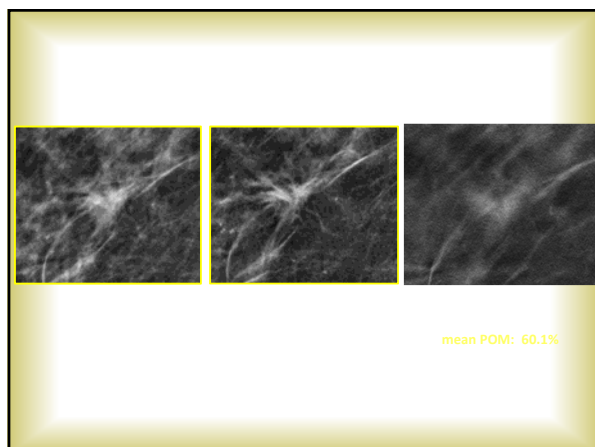
8/15 readers recalled



mean POM: 14.4%
(probability of malignancy)





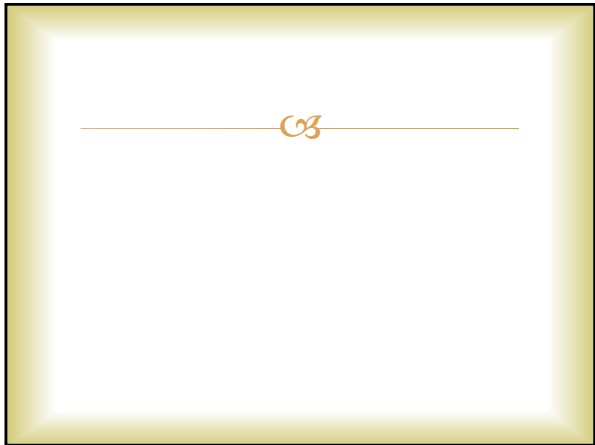


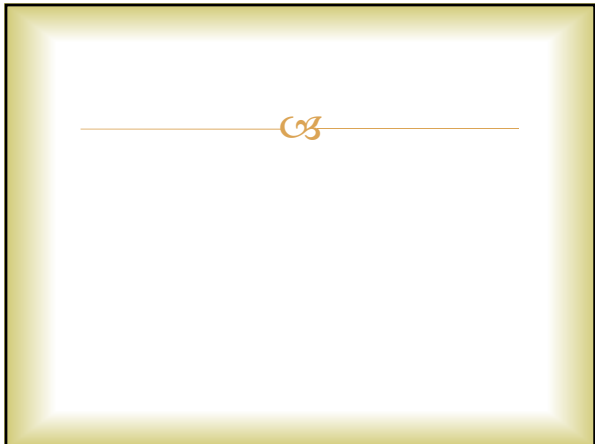
Rationale for 3D plus *C-View

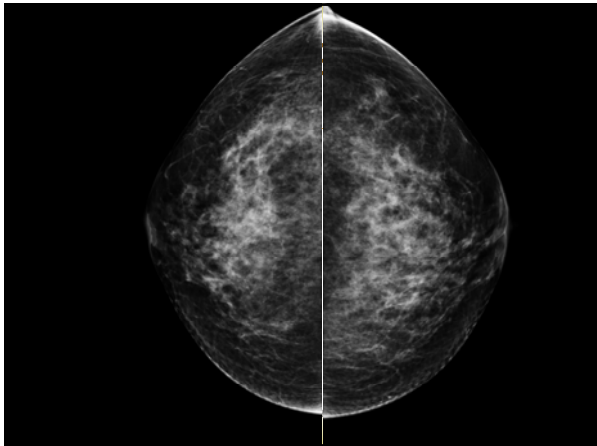
- The advantage of two-view tomosynthesis while reducing dose and capitalizing on the benefits of 3D
- Value of a 2-dimensional "summary" image:
 - Assessment of side to side symmetry
 - Assessment of interval change
 - Detection of calcifications
 - Recognition of the distributional aspect of features (particularly calcifications)

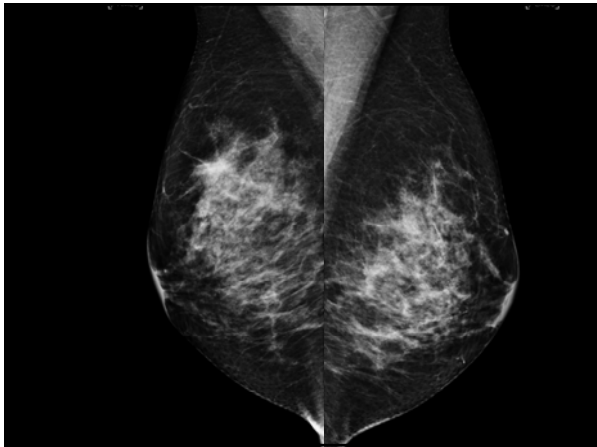
*Not approved for sale in the United States

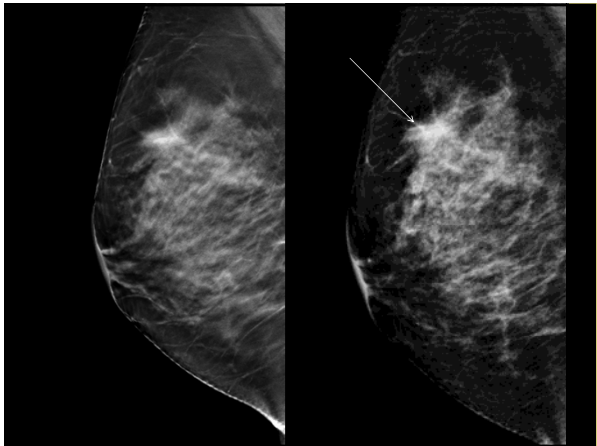


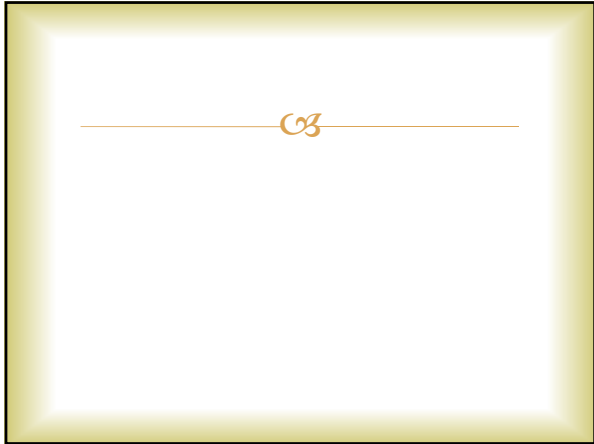


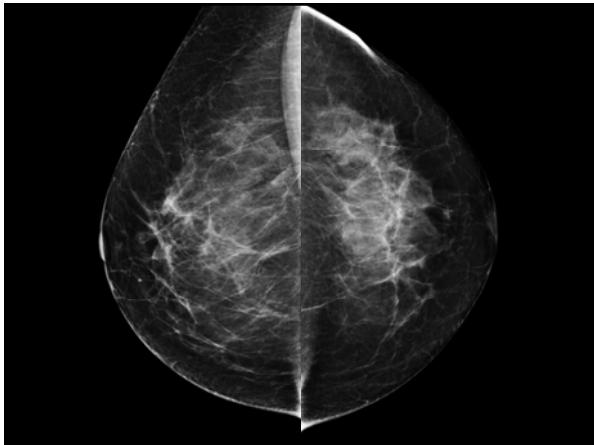


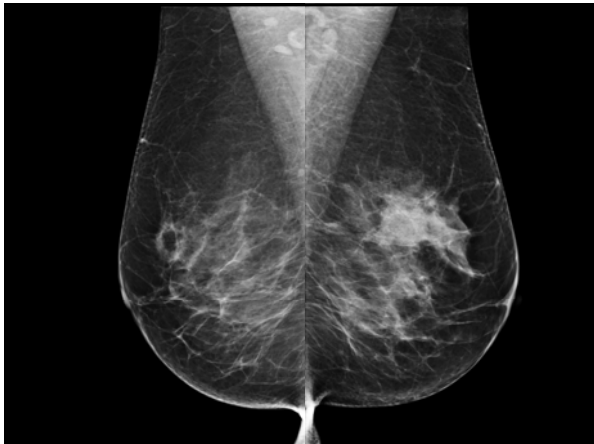


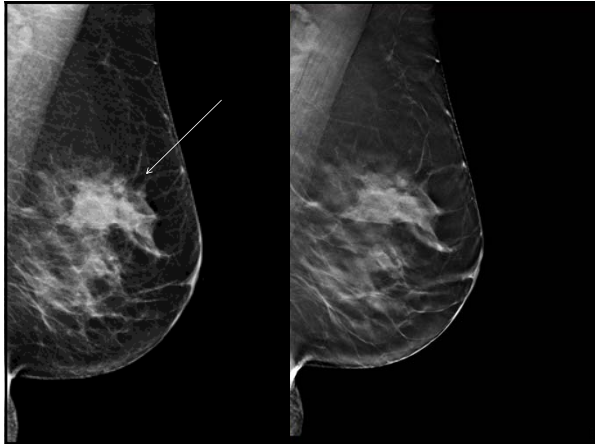


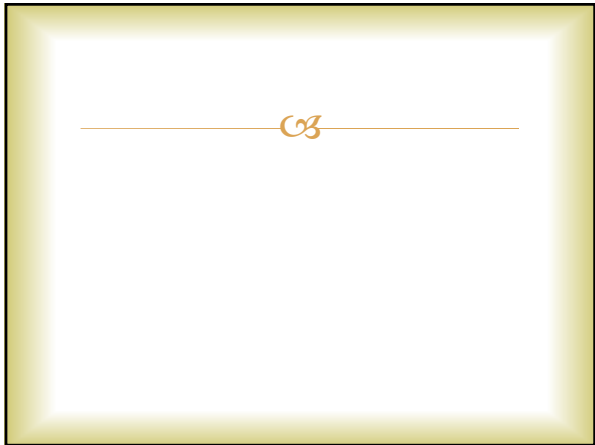


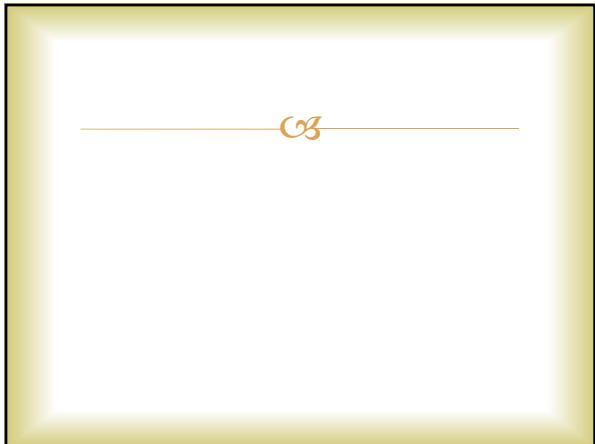


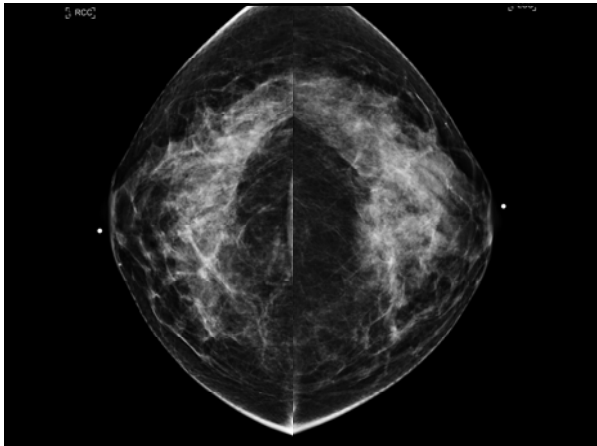


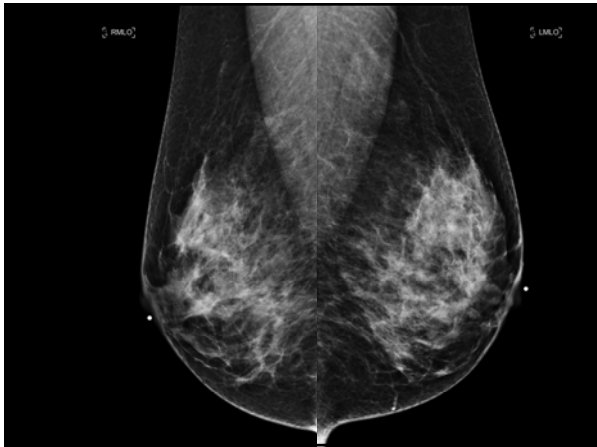


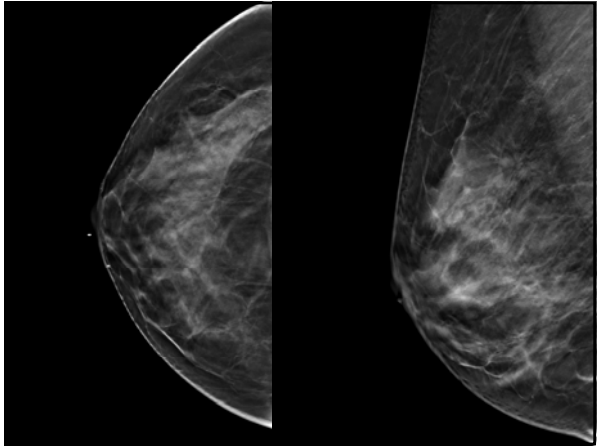


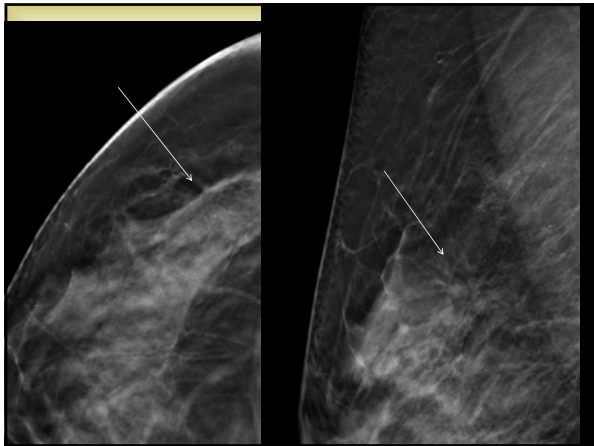


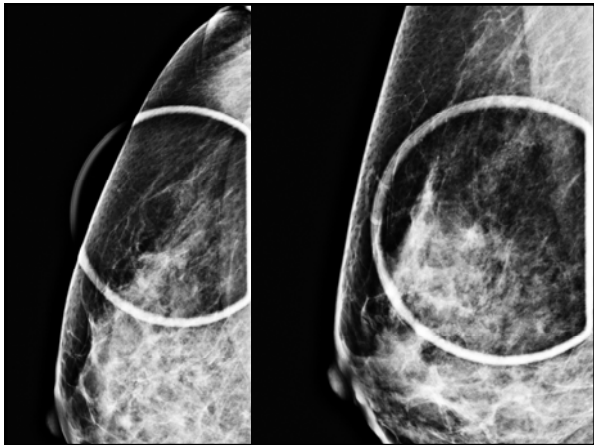




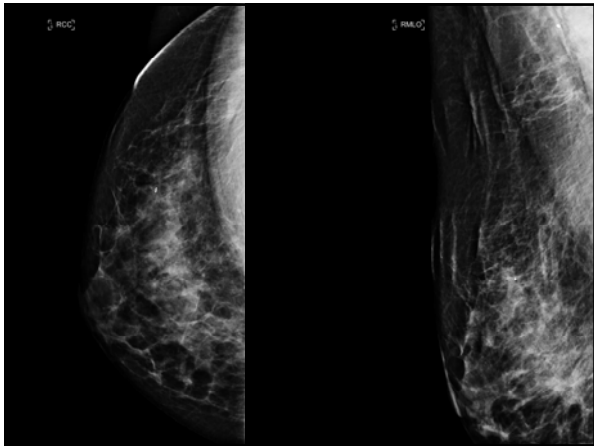


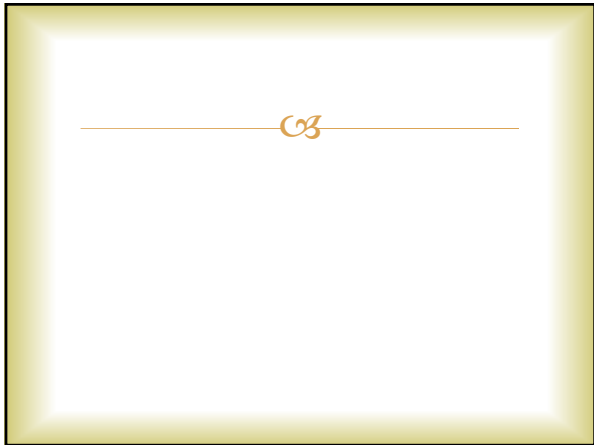


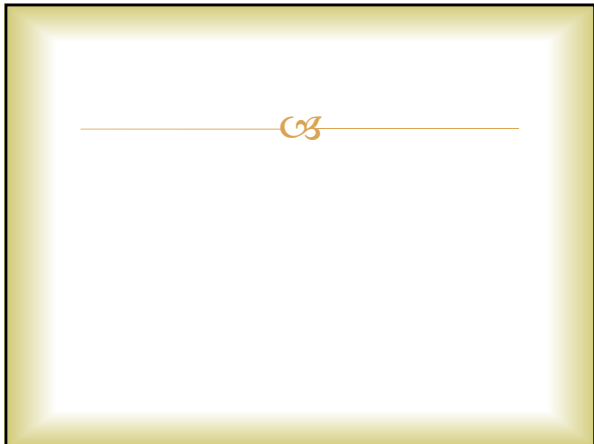


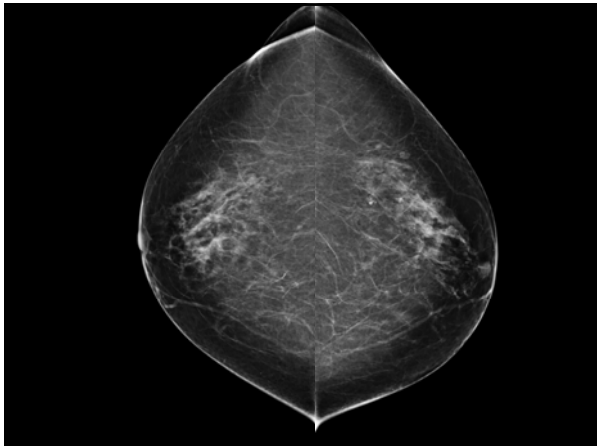




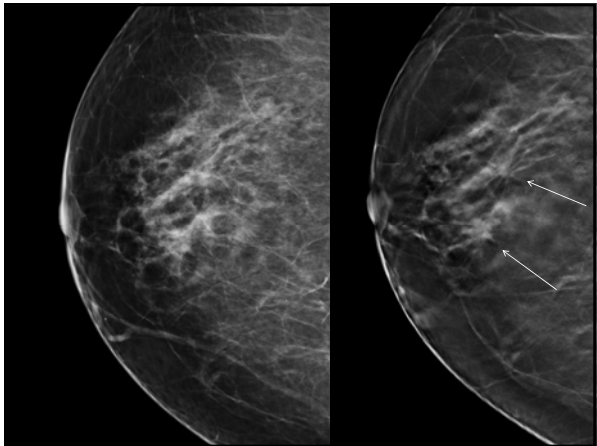


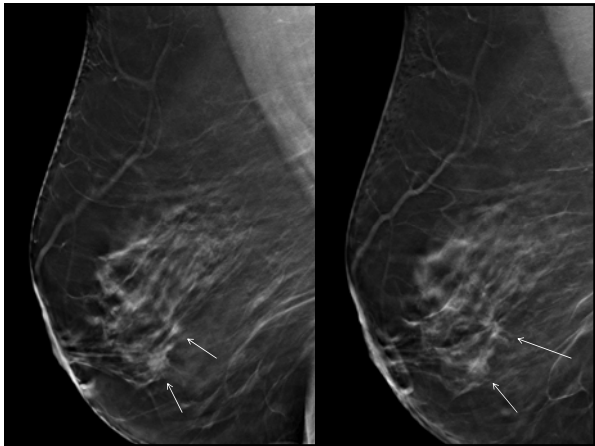


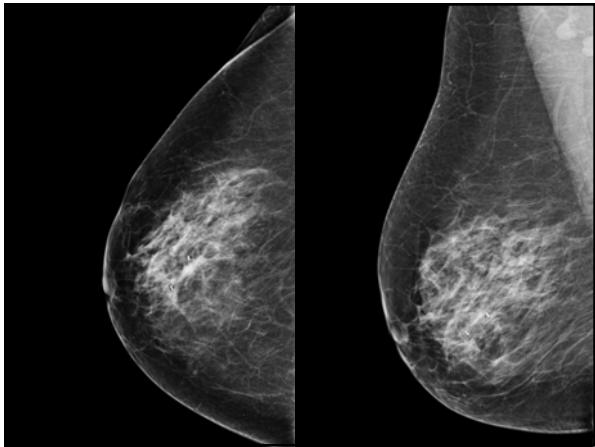


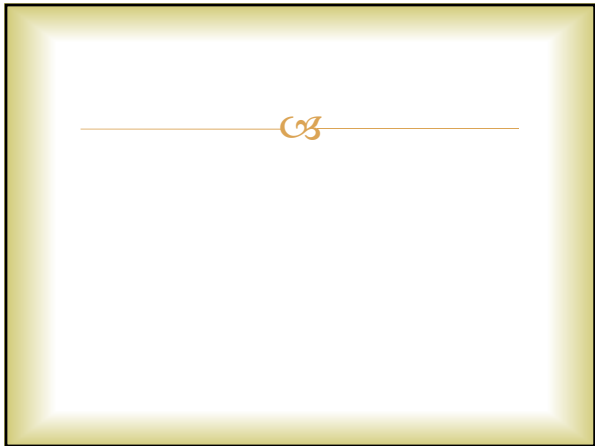


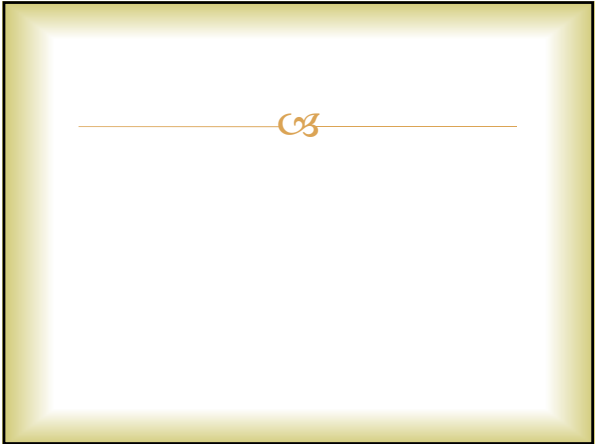


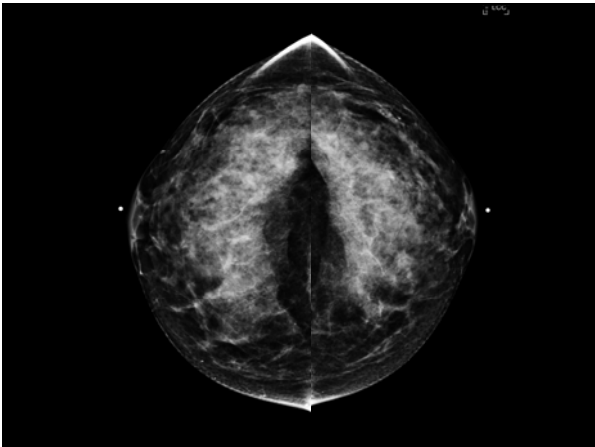


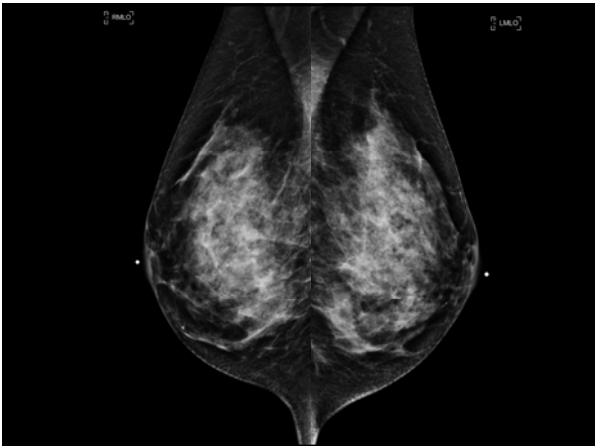


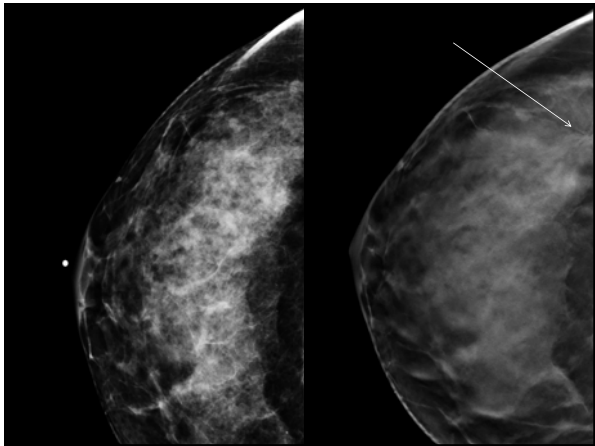


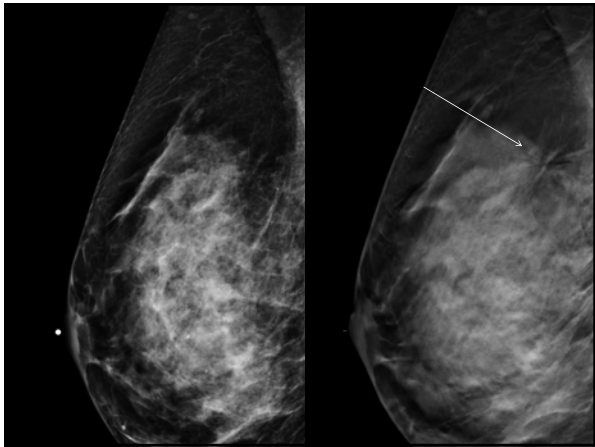


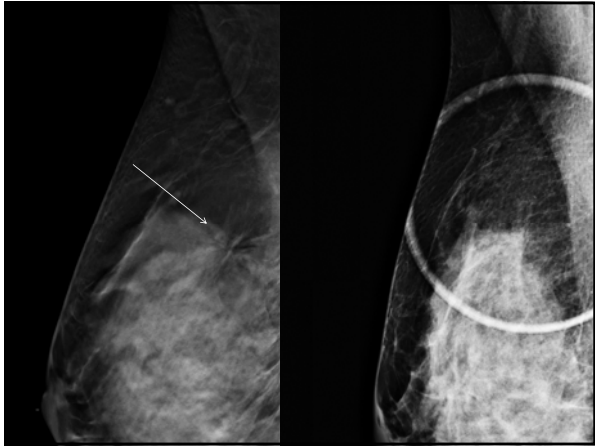


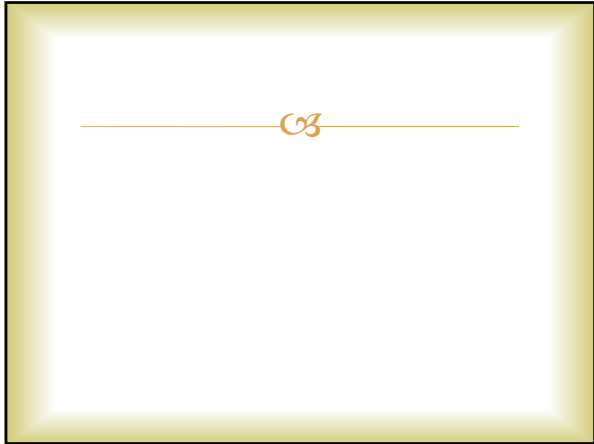


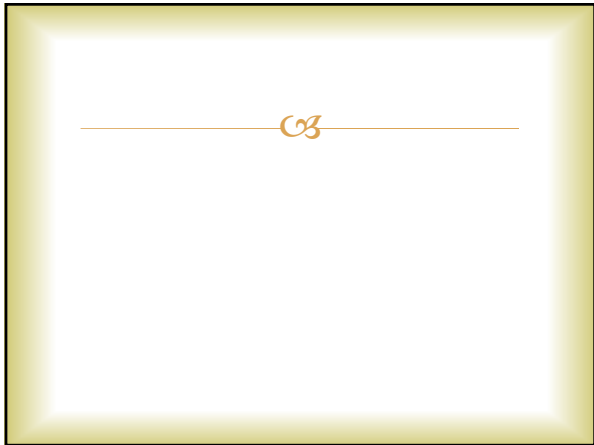


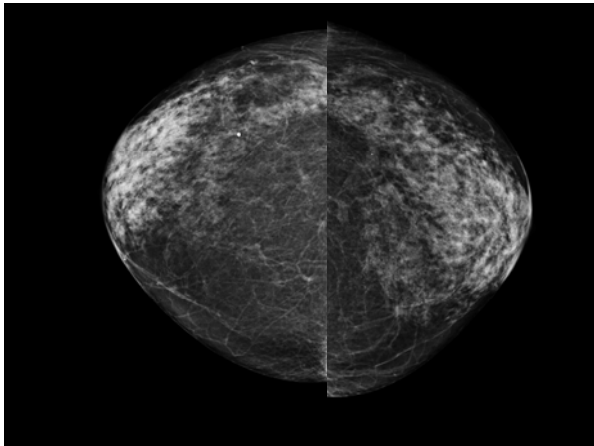


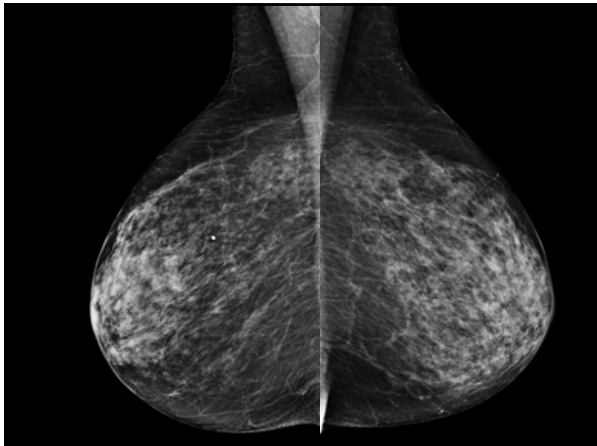


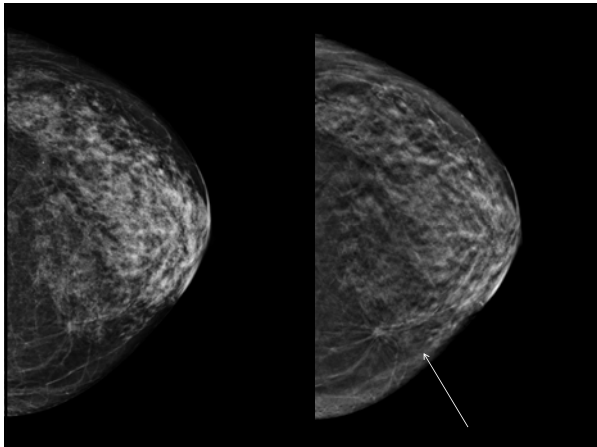


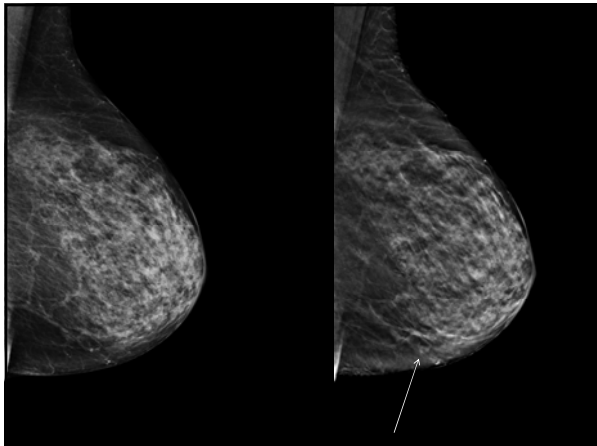


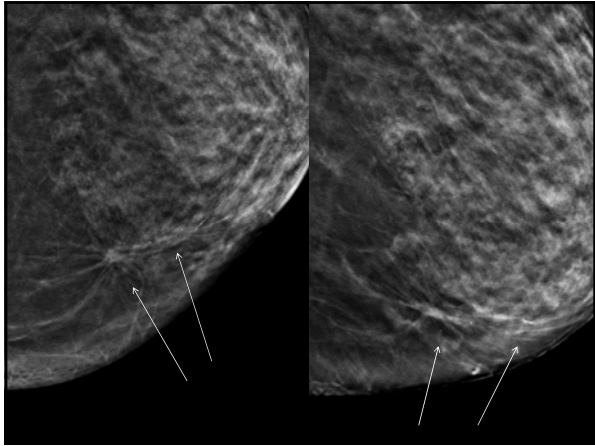


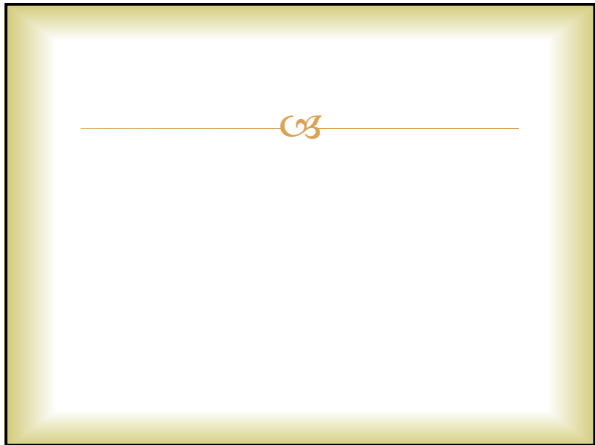




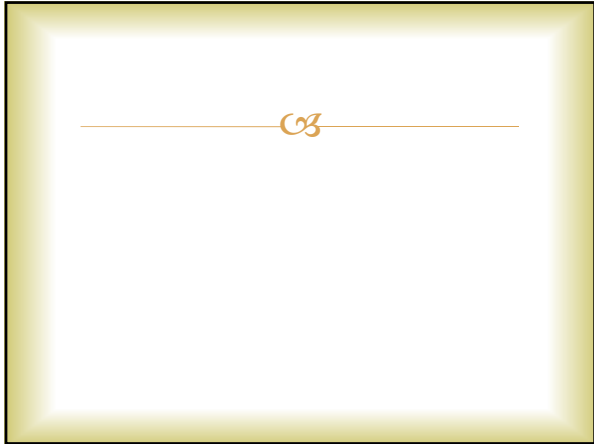


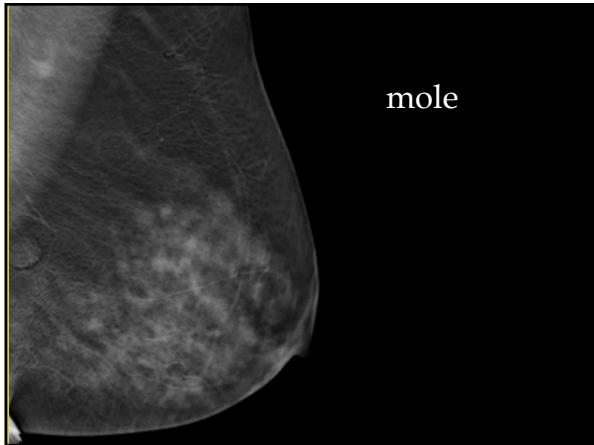


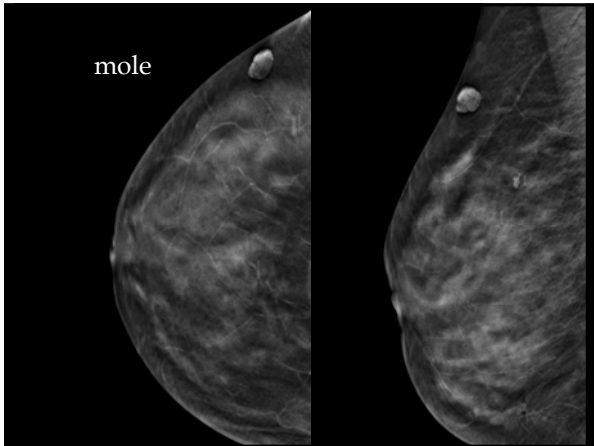


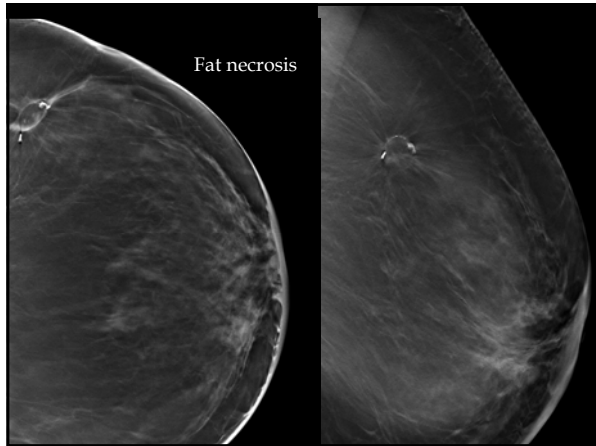


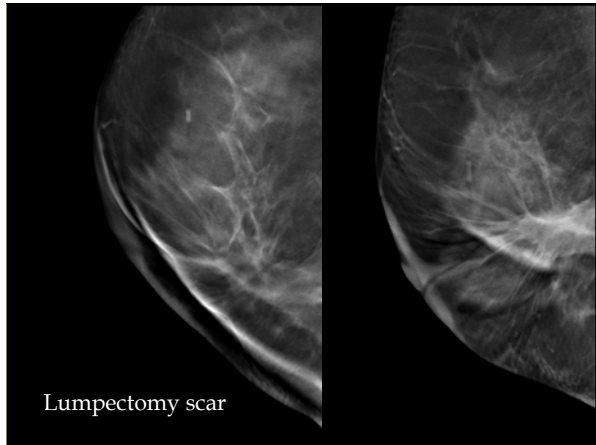


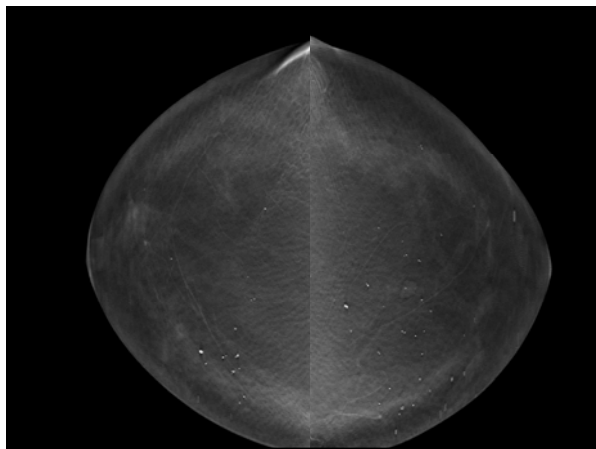


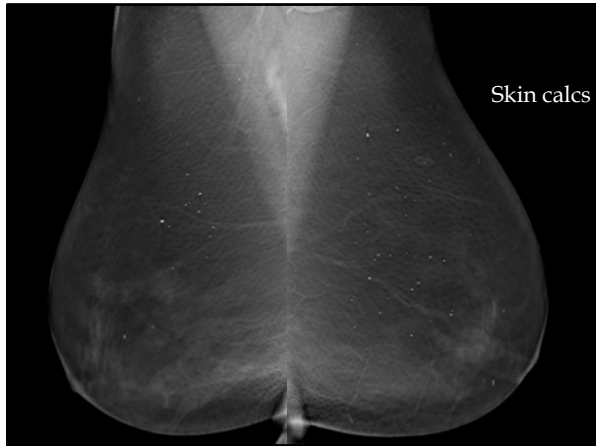


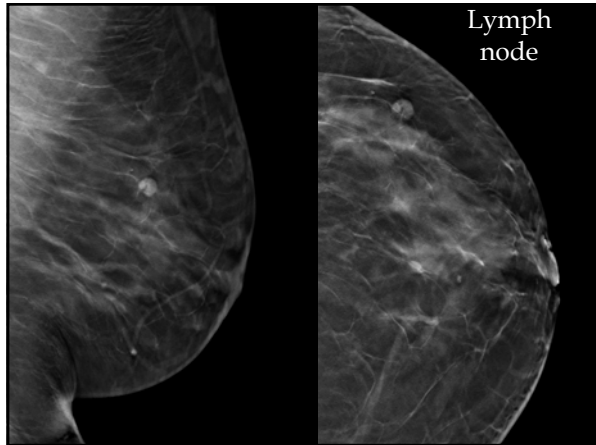


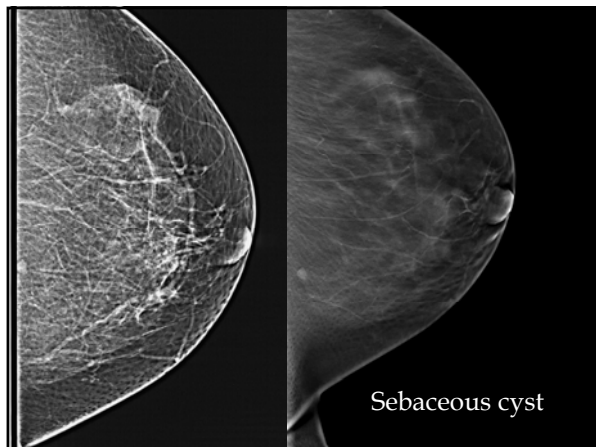




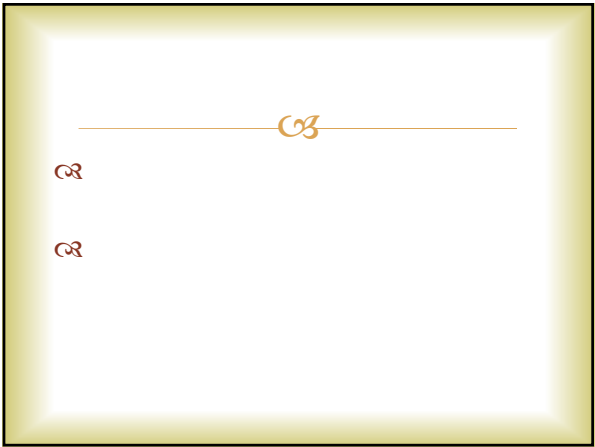


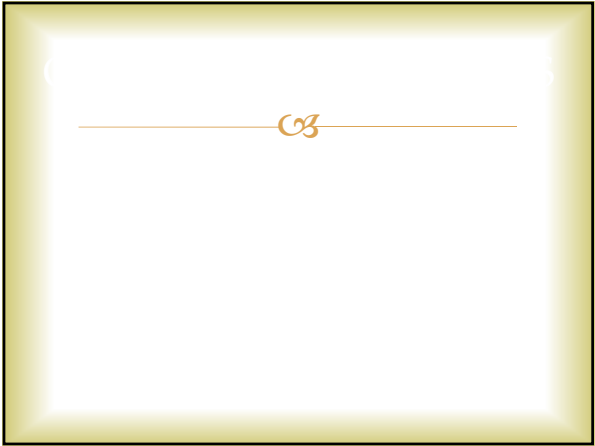




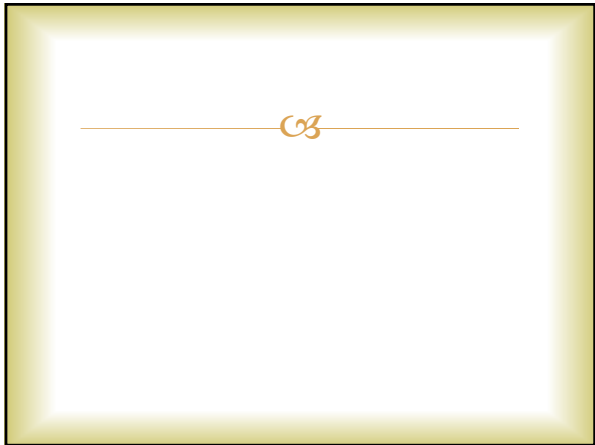


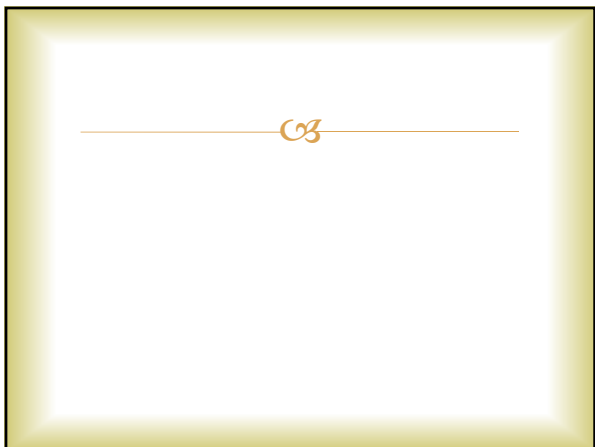


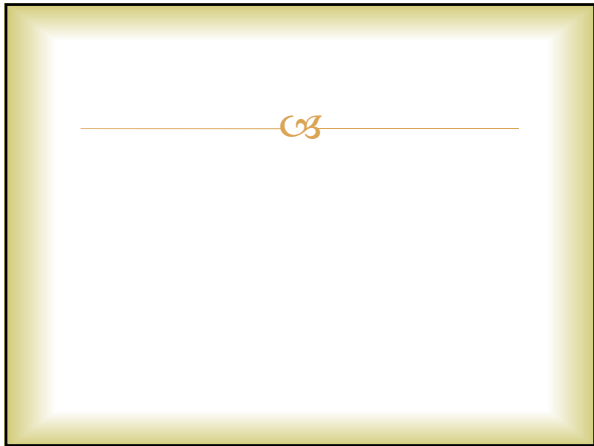




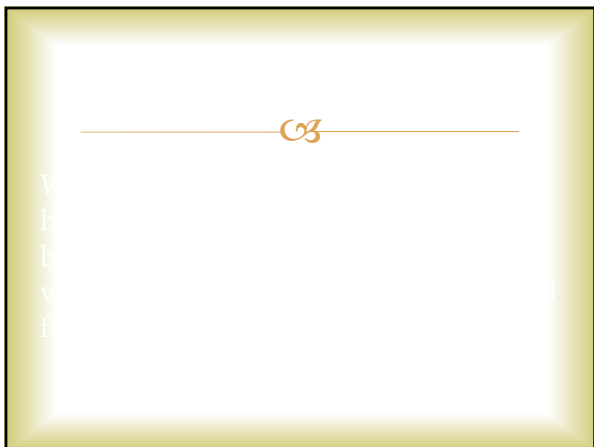


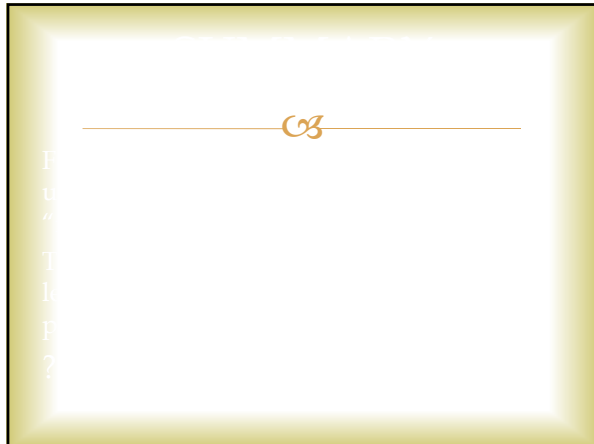


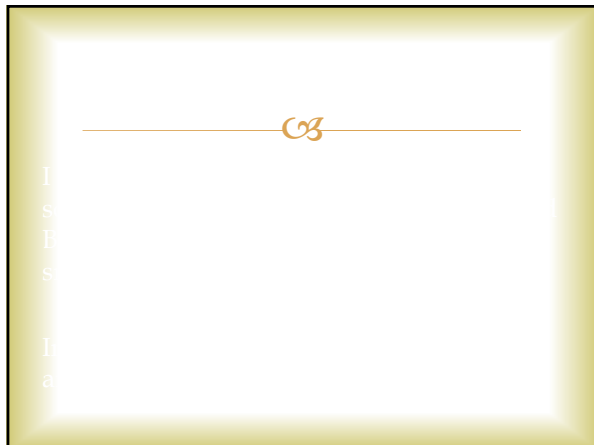














The radiation dose for combo mode (2D plus 3D) is:

0%

1. 1.45 mGy

0%

2. 2.65 mGy

0%

3. 4.85 mGy

0%

4. 8.85 mGy

0%

5. 10.65 mGy

10

ANSWER

2.65 mGy

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/RadiologicalDevicesPanel/UCM226757.pdf>

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One of the major benefits of 3D imaging is:

0%

1. Lower radiation dose per case

0%

2. Better visualization of calcifications

0%

3. Less compression

0%

4. Elimination of superimposed normal tissues

0%

5. Easier positioning

10

ANSWER

Elimination of superimposed normal tissues

Kopans. Breast Imaging, 3rd edition. Lippincott Williams and Wilkins

115

The one thing that C-View would NOT
be helpful for would be:

- 0% 1. Decreased radiation dose by about 50%
- 0% 2. Better visualization of smooth/benign masses
- 0% 3. Accentuation of distortions and calcifications
- 0% 4. Comparison to prior 2D exams
- 5. Guide for viewing the 3D image set

10

ANSWER

Better visualization of smooth/benign masses

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/RadiologicalDevicesPanel/UCM325901.pdf>

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The major findings of the Oslo study regarding 2D imaging vs 2D plus 3D imaging for screening were:

0%

1. There were no advantages to including 3D imaging in their population

0%

2. There was a 40% increase in the invasive cancer detection rate

0%

3. The detection rate for noninvasive cancers fell by 10%

0%

4. 3D imaging was only helpful in denser breasts

5. The call back rate for additional imaging increased, due to better visualization, by 25%

10

ANSWER

There was a 40% increase in the invasive cancer detection rate

- Comparison of Digital Mammography Alone and Digital Mammography Plus Tomosynthesis in a Population-based Screening Program. Skaane P, Bandos AI, Gullien R, et al. Radiology, 2013 Jan 7. [Epub ahead of print]

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What is the one thing we have NOT FOUND since tomosynthesis was introduced:

- 0% 1. Decreased call back rate for additional mammographic imaging by about 40%
- 0% 2. More BR3 (probably benign) results
- 0% 3. Increased cancer detection rate (40% for invasive cancers, by Oslo study)
- 0% 4. Stable call back rate for ultrasound examinations
5. Increased positive predictive value for biopsies of about 35%

10

ANSWER

More BR3 (probably benign) results

- Rose S, Bujnoch L, O'Toole M, Nordmann A, Sexton R, Willison K, Tidwell A. Breast Tomosynthesis and Digital Mammography for Breast Cancer Screening: Medical Outcomes Audit. Presented at RSNA 2012, VSB41-06 Breast Series: Emerging Technologies in Breast Imaging
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